UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/333,534	06/14/1999	TIMOTHY W. CONNER	38-21(15404)	4215

7590 08/05/2002

LARRY M LAVIN JR
MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH BB4F
ST. LOUIS, MO 63198

EXAMINER
MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 16

Serial Number: 09/333,534
Filing Date: 6/14/99
Appellant(s): Conner et al.

Lawrence M. Lavin, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 5/1/02.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The amendment after final rejection, filed on 5/1/02, has been entered.

(5) *Summary of invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct. The entry of the after final amendment, filed on 5/1/02, has overcome the formality issue regarding hyperlinks.

(7) *Grouping of claims*

The appellant's statement in the brief that only claim 1 remains in this application and that because no other claims are pending, therefore claim 1 does not stand or fall with any other claims is agreed with.

(8) *Claims appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of record*

No prior art are relied upon by the examiner in the rejection of claims under appeal.

(10) *New prior art*

No new prior art has been applied in this examiner's answer.

(11) *Grounds of rejection*

The appellant's statement of issues in the brief is correct.

(12) *New ground of rejection*

This examiner's answer contains no NEW GROUND(S) OF REJECTION.

(13) *Response to arguments:*

LACK OF UTILITY UNDER 35 U.S.C. § 101

Arguments regarding the rejection of claim 1 based on a lack of utility under 35 U.S.C. § 101. These are mixed with arguments regarding lack of written description in appellant's brief and are responded to below in the order in which arguments regarding utility are present in said mixed appellant's brief.

The basis for this rejection is that the asserted utilities of the claimed invention are neither specific nor substantial and are generally applicable to generic nucleic acids. Appellant argues firstly that the Supreme Court in *Brenner v. Manson* said that a patent monopoly is granted where specific and substantial benefit exists in currently available form. In response this is acknowledged but is lacking in appellant's disclosure regarding the specific and substantial benefit. Appellant goes on to argue that at least one specific benefit has been supplied in the form of the identification of the presence or absence of polymorphisms. In response, this is not a specific utility for two reasons. Firstly, any nucleic acid supplies the benefit of either being hybridizable to its complement in a sample, if it is present, or not hybridizing if the complement is not present in said sample as well as not hybridizing under the appropriate stringency conditions if a polymorphism is present in the sample

nucleic acid which corresponds to non-complementary sequence(s) in the sample. Therefore, appellant's asserted utility is clearly non-specific and a property of any generic nucleic acid thus supporting this rejection.

Appellant then argues that the claimed nucleic acids have legal utility starting on page 4, part B, of appellant's brief. After summarizing previous Office Actions, appellant argues that the Examiner's analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility". Appellant further argues that the threshold for utility is not high and that an invention need only provide one identifiable utility, citing various legal documents. In response this is acknowledged, with the clarification that such an identifiable benefit must be specific and substantial, but no such identifiable utility has been found is these statements. Additionally, even a low threshold is not exceeded by an invention which lacks specific and substantial utility. In the first full paragraph on page 5 of appellant's brief several citations in the specification have been set forth as to providing identifiable benefits. Each of these citations are now commented on as follows: The first citation is on page 37, line 23, through page 45, line 15. On page 37, line 23, the specification starts with the analysis of the presence or absence of a polymorphism as being associated with a phenotype or a predisposition to phenotype. In response, what phenotype is meant? No specific or even vague inference of any specific or

substantial phenotype has been set forth as associated with the claimed nucleic acids. Is appellant hoping and wishing that some phenotype is associated with a polymorphism or with any of the claimed ESTs? None have been set forth. Even if there is an associated phenotype, research is required in order to identify it out of the myriad of possible phenotypes. Thus, this utility is neither specific nor substantial and at best may be the basis for a research project, albeit with unknown direction. Thus, this utility is also not in currently available form as required by *Brenner v. Manson*. Then, in the specification on pages 38-45, polymorphisms and methods for their detection are generically explained but without any linkage to any of the claimed nucleic acids. Thus, pages 38-45 lack any specific and/or substantial disclosure of an association between the claimed nucleic acids and any polymorphism. Further research would be required in order to find any such association, if any exist, regarding the claimed nucleic acids. This need for further research is also evidence of a lack of utility in currently available form. The second citation is on page 45, lines 16-26, and asserts the usefulness of genetic markers in forming a map for linkage analysis, screening of populations, etc. In response such genetic markers are useful only if they mark a genetic location that is defined in the genome being marked. No marker locations have been set forth for any of the claimed nucleic acids. What do they mark? Where do they mark in the plant genome? What significance or utility, if any, is present for a marker where

what is marked is undefined and unknown? Further research may define marker locations in a genome, but even this is unclear because there is no information as to whether the claimed nucleic acids may or may not be present in multiple copies or a single copy as to location(s) within a genome. Therefore, the use of any of the claimed nucleic acids as a marker is speculative at best even with further research. Within this section appellant also argues that expression profiling as a hybridization probe is a usage for the claimed nucleic acids. In response no specific or substantial association has been set forth for any expression increase, decrease, or constant expression as may be assessed via the claimed nucleic acids as probe(s). Thus, again further research is required, if there is any significance, regarding expression effects, thus well documenting the lack of a currently available utility, if it even exists, after research.

Starting in the middle of page 5, appellant's brief alleges that a specific benefit is supplied by the claimed nucleic acids in the form of additional utilities citing the specification at page 78, line 24, through page 80, line 2. In said citation the co-suppression of endogenous protein was described via antisense methodology. This methodology was generically described on pages 79-80 but without any indication as to what specific and substantial antisense activity is supplied by any of the claimed nucleic acids. Not even one endogenous protein was discussed regarding any of the claimed nucleic acids that may be co-suppressed thus lacking in specificity of utility. No indication

as to whether co-suppression could even be performed for any of the claimed nucleic acids thus again lacking in substantial utility disclosure. The screening or monitoring of control versus antisense treated plants were indicated in the bridging paragraph between pages 5 and 6 of the brief. In response such an experiment is clearly further research and further documents the lack of currently available form utility for the instantly claimed nucleic acids. Further, even if the experiment was performed what would be screened or monitored? What characteristic or phenotype would be assessed in such an experiment in order to define some type of association to the antisense nucleic acid? Each plant has a myriad of characteristics that could be monitored or screened. Such a screening or monitoring experiment thus has no specific or substantial place to start the analysis by which even a possible association with a claimed nucleic acid may be determined. Thus, this allegation again falls short of defining either a specific or substantial utility for any of the claimed nucleic acids.

Appellant then indicates that the Office Action, mailed June 5, 2001, at page 5 acknowledges several other uses in the specification. In response neither appellant nor said Office Action acknowledged or described even one specific or substantial utility therein.

The bottom half of page 6, including footnotes, of appellant's brief reiterate the polymorphism utility as well as the marker utility issue. These both have been responded to

above as lacking in defining either specific or substantial utility. No further disclosure has been supplied as to specific or substantial utility. For example, drought stress profiling was alleged as a use in a microarray format for EST sequences. No drought stress profile has been set forth for the instantly claimed nucleic acids. Thus, further research would again be required to discover any such profile result, if it exists. Which of the instant nucleic acids are associated with drought stress, if any? Markers are also discussed at the bottom of page 6, but again without any specific or substantial effect being instantly disclosed as to being marked.

Starting on page 7 of appellant's brief, appellant then sets forth the analogy of a microscope as having utility as a research tool equivalent to the instant invention. This analogy does not fit the instant fact pattern. The microscope, in contrast to the instant invention, has already been established as having numerous well known utilities. One of these is the examination of biopsy tissue for cancer diagnosis. Cancer diagnosis is certainly a well established utility. Other such utilities for diagnosis are well known such as blood typing usage, for example. For these utilities a measurable result is obtainable which is associated with a disease or patient condition. The list goes on extensively for utilities of a microscope. Such utilities for a microscope well document its usefulness as a research tool due to the well established analysis completion that is doable while utilizing a microscope. These practical and well established

utilities have neither been developed nor well known for the instantly claimed nucleic acids. None of the instantly claimed nucleic acids have been established regarding plant disease diagnosis, for example, nor whether or not they are specifically or substantially linked in any way to plant growth, plant usage, etc. Further research is required to firstly even suggest such linkages, followed by more research by which to verify such linkages. Appellant is apparently seeking a Patent for a hunting license for the utility for the claimed invention and has not set forth even one successfully found utility in currently available form.

Appellant then compares the gas chromatograph to the instant invention. Again the analyses that may be performed utilizing a gas chromatograph are well known to be useful in chemical analyses including identification of chemical structure, for example. No such utility has been asserted or is well known for the instant nucleic acids. Appellant then argues again regarding polymorphism detection usage. The lack of utility due to this asserted utility being non-specific and non-substantial has been already responded to above and is reiterated here. Appellant adds the argument that a demonstration of the absence of a polymorphism between two samples usefully demonstrates a common genetic heritage. In response this utility, firstly, has not been set forth as filed. Secondly, this is a generic characteristic that is available for generic nucleic acids and therefore not specific to the claimed nucleic acids per se.

Thirdly, further research would be required for determination of a common genetic heritage because the absence of a polymorphism in a sample may be due to only one of two alleles being analyzed wherein the other allele may or may not support the common genetic heritage. Thus, this asserted utility again requires further research and is not in currently available form.

Starting in appellant's brief at page 8 appellant argues that the initial burden of challenging the operability has not been met regarding polymorphism detection. In response, operability of what? There has not been any disagreement that nucleic acids generally are useable and operable for polymorphism detection, if they exist. The issues regarding this rejection are that the asserted utilities are non-specific and non-substantial. Operability has not been questioned for the non-specific and non-substantial uses of nucleic acids generically. Therefore, this argument is moot due to its being not directed to the basis of this rejection. In the second full paragraph on page 8 of appellant's brief, the statement is made that the benefit of polymorphism detection, via the claimed nucleic acids, is not a use of other molecules. It is not understood why other molecules which clearly must include other nucleic acids are not generically usable in polymorphism detection, if any are present in the target region(s) for any nucleic acid utilized as a probe. Appellant has not negated or argued that such detection is mediated by the complementarity of nucleic acids that is capitalized on during hybridization assays. Thus, the statement

of appellant that polymorphism detection using other nucleic acids is not available as a use, when such polymorphic differences exist between samples, is cleanly contrary to well established scientific facts.

In the bridging paragraph between pages 8 and 9 of appellant's brief the argument is set forth that the claimed nucleic acids may be used for hybridization usage for isolation of nucleic acids from other plants and organisms such as alfalfa etc. In response this is a generic usage for any nucleic acid via complementary sequence therein and therefore non-specific. Additionally, if any generic nucleic acid including those instantly claimed were to be utilized in the isolation of a complementary nucleic acid in alfalfa, for example, then what? Since the claimed nucleic acids have not been associated with any specific or substantial gene, characteristic, protein, etc. only further research may or may not illucidate a use for any isolated nucleic acid. Thus, again it is clear that appellant has failed to set forth any currently available, specific, and substantial utility.

On page 9, first full paragraph, of appellant's brief a chromosome walk or promoter isolation are argued as uses for the claimed nucleic acids. Such chromosome walks or promoter isolations are further research again documenting the lack of a currently available utility. Any nucleic acid may be generically applied to such procedures. Nothing specific or substantial has been set forth, even if such a chromosome walk or promoter

isolation occurred. What utility would a promoter to an unknown gene have? Only further research may or may not uncover a utility. Appellant then argues that exclusive utility is being required in this rejection. This argument is moot as not directed to the basis for the rejection which is the lack of specific and substantial utility without any exclusivity being required.

Appellant then argues at the top of page 10 of appellant's brief that an active promoter may be identified by a chromosome walk. This is firstly an allegation without factual support that such an active promoter may be found. Secondly, the finding of such a promoter would be further research and thus not in currently available form. Thirdly, even if an active promoter were found, the question still remains, a promoter of what? A myriad of promoters are present in complex organisms and are non-specific as well as non-substantial entities until further research determines some function regarding the gene to which they are connected. Also, it is speculation that a promoter may be found because multi-cistronic gene sets are well known where no promoter is connected to many genes, but rather a complex operon promoter may be utilized therein and exceeding difficult to find and delineate. In any case, none of the instant nucleic acids have been described regarding what chromosome walking will find. It is speculative and again requiring further research which is not a currently available utility.

In appellant's brief in the bridging paragraph between pages

10 and 11 a focus on alternative wording for utility requirement such as practical or real world utility is argued. These are equivalents to specific and substantial and are not seen to alter the basic inquiry regarding the lack of utility rejection as applied to the instant invention.

In the first full paragraph on page 11 of appellant's brief the polymorphism detection utility is again argued. This has been already responded to above and said response is reiterated here. Appellant has, however, conjured up another concept regarding polymorphism detection, that is, determining the distribution of parental genetic material in the progeny of a cross. In response, firstly, this determination of parental genetic material use apparently was not contemplated as filed. Secondly, any particular nucleic acid may or may not be that of a parent in a cross. The disclosure of a nucleic acid does not itself determine whether both, or neither, parents in a cross contain the nucleic acid or its complement. Thus, the mere disclosure of nucleic acids as instantly claimed fails to document that any of them have any usage in such parent/progeny determination. Again, further research is required by which to determine whether any of the claimed nucleic acids are useful in such a determination. Due to this need for research, any and all generic nucleic acids are equally likely to correspond to a parental genetic material. This equal liklihood causes the possibility of this utility of a generic nucleic acid to be the same as for the claimed nucleic acids again documenting the non-

specific as well as non-substantial character of such polymorphism determination. This supports this lack of utility rejection.

Starting in the middle of page 11 of appellant's brief and extending to the top of page 12, the commercial value of ESTs is argued. In response, none of the instant ESTs per se as claimed have been connected with commercial value. The commercial value of other ESTs is undoubtingly supported by the completion of further research which has defined a specific and substantial use for them. Appellant's apparently are unwilling to either acknowledge this or unable or unwilling to do the research that would supply value to the claimed ESTs. Appellant argues that fermentation processes utilize ESTs etc. but while ignoring what basis was used for selection of any such utilized EST(s). Apparently appellant is arguing that industries that perform fermentation arbitrarily toss ESTs into their fermentation mixes without knowing a purpose for such an additive. It is again pointed out that the instant ESTs have not been researched as to what effect(s) they might have on a fermentation and thus again lack specific or substantial utility, even for fermentations.

On page 12, first full paragraph, of appellant's brief the issue of credible utility is argued. This rejection is based on a lack of specific and substantial utility and thus arguments regarding credibility are moot. It is noted that a utility may be credible and yet lack specific and substantial utility and therefore be properly rejected as lacking utility. It is

acknowledged that the asserted utilities for the instant invention lack specific and substantial utility although they are credible utilities because they are not "hare-brained" utilities as noted by appellant. This does not, however, negate the lack of specific and substantial utility and does not overcome this rejection.

In summary, appellant has set forth a claim to ten ESTs which have been characterized only regarding their sequence and nothing else. A plurality of asserted utilities have been set forth but without the completion of any of the required research by which to potentially result in either a specific or substantial utility in a currently available form. In connection with this, it is noted that research does not guarantee the finding of a useful result, even if it is performed. That is why it is called "research". A multitude of research projects end in failure, even sometimes after years of work. Thus, there is clearly no currently available utility that has been set forth by appellant that is specific or substantial for the instant invention.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Arguments regarding the rejection of claim 1 based on a lack of enablement under 35 U.S.C. § 112, first paragraph. This rejection is based on the above lack of utility as also therefore supporting a lack of enablement for the claimed invention. Appellant has not argued this rejection other than pointing to the arguments regarding the lack of utility. Therefore, these

arguments have already been responded to above and are reiterated here as equally non-persuasive.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

It is firstly noted that instant claim 1 is directed to nucleic acid molecules which each encode a protein from *Arabidopsis thaliana*. Each of the claimed nucleic acids are described only to the extent of an EST sequence. None of the ten EST sequences contain a complete coding region for a protein. That is, there is no combination of start codon, stop codon, with intermediate coding sequence, and they are generally shorter than that required for a full normal protein coding sequence. Thus, in order to encode a protein from said plant, more flanking and undisclosed sequence information is required. This additional flanking sequence does not have written description as filed.

On page 3 of appellant's brief a section regarding this rejection is argued in that the SEQ ID NOs. 1-10 serve to distinguish the claimed genus of molecules from molecules not in the claimed genus. In response the claim does not indicate any genus limitation or analysis. Further the issue regarding this rejection is the lack of written description and not whether there is or is not a genus distinguishing usage for the claimed invention. This argument is therefore moot due to not being directed to the basis of this rejection.

Starting on page 13, Part D, of appellant's brief, the appellant firstly acknowledges that the sequence information in

SEQ ID NOs. 1-10 per se have been indicated as properly having written description. It is noted that the lack of the above discussed flanking sequences by which to obtain a protein, rather than only a segment thereof, is the basis of this rejection.

Appellant then argue that "comprising" claim wording is a proper claim wording. This is acknowledged, but is not the basis for this rejection and therefore moot. Such comprising claim wording is well known as proper and common claim wording, but does not cure the lack of flanking sequence description by which to describe at least the coding sequence for proteins of *Arabidopsis thaliana*.

On page 14 of appellant's brief, appellant argues that the inventors had possession of SEQ ID NOs. 1-10 and therefore had possession of the claimed invention. In response, it has already been acknowledged that SEQ ID NOs. 1-10 per se have written description, but these sequences are not the entirety of the claimed invention. These sequences are only EST subsegments of the nucleic acid molecules that encode proteins of *Arabidopsis thaliana*. By way of more specific illustration of this lack of written description, the smallest sequence is that of SEQ ID NO: 5. It is only 79 nucleotide bases long and clearly can be easily seen by rapid inspection to lack a start codon, or significant coding length, as required for a full coding sequence for a protein. It is acknowledged that this may be an EST from the 3' end of a protein coding region because it ends with "tga" which is one of the possible stop codons, but as noted above there is

no significant length to SEQ ID NO: 5, nor start codon seen. Even this "tga" may not be a stop codon as there is no way to determine what coding frame should be utilized to define any potential triplet codons for this EST. Two out of the possible three reading frames for this EST would not have a stop codon at the 3' end thereof. Only one out of the three possible reading frames would have a potential "tga" stop codon at the 3' end of the claimed nucleic acid.

In the bridging paragraph between pages 14 and 15 of appellant's brief appellant continues to argue that the inventors had possession of SEQ ID NOs: 1-10. This is acknowledged. Appellant further argues that the claim covers molecules that hybridize under specific conditions to the recited sequences. This is not seen in the claims and is therefore non-persuasive as being directed to subject matter which has not been claimed and not the basis for the rejection also.

In the first full paragraph on page 15 of appellant's brief the specification at pages 3, 10-12, 15, 27-31, 61-69, and 81 are pointed to regarding vectors comprising the claimed nucleic acids as well as libraries utilized to make them, extra nucleotides, and detectable labels. In response, consideration of said cited pages has failed to reveal any more nucleotide sequence by which to complete the written description of the coding regions for the nucleic acids as claimed. The basis for this rejection is a lack of written description regarding the required sequence for coding the proteins as cited in instant claim 1. None of this added

flanking sequence has written description as filed. The comprising language in claim 1 is acknowledged as being directed to the addition of vector sequences, for example, for containing the claimed SEQ ID NO: sequences. This comprising open claim language coverage of such subject matter is not the basis for this rejection. Thus, the additional discussion/argument regarding the open claim language is not directed to the basis for the rejection and therefore moot and/or non-persuasive.

On page 16 of appellant's brief, first two paragraphs, the possibility of other sequence species and methods of obtaining variants and other sequence information giving support for the instant invention is argued. In response such variants as well as methods of making still lack the specific written description for the now claimed protein coding nucleic acids regarding sequence beyond SEQ ID NOs: 1-10 per se. Appellant's arguments have not filled in this additional sequence from variants or methods of making other sequences and thus still lack written description as summarized above.

In the bridging paragraph between pages 16 and 17 of appellant's brief and the remainder of page 17, appellant argues that the genus of nucleic acids as claimed have been described and therefore nothing more is required. In response only a subsegment of the coding regions of the claimed nucleic acids has any description. There is nothing to delineate or describe the genus beyond SEQ ID NOs. 1-10. There is no genus descriptions of coding region lengths. There is not even one example of a full

protein coding sequence as filed regarding the claim 1 nucleic acids, nor what expected genus variations might occur from such a sequence. It is again noted that claim 1 is directed to nucleic acid molecules that encode a protein of a specific plant and not of any other organism, or plant, for that matter. In order to have written description of such a genus of nucleic acids at least some information is required as to written description regarding the encoded proteins beyond merely a subsegment thereof. Nothing, however, beyond the explicit SEQ ID NOs. 1-10 have written description as filed and thus the protein coding nucleic acids for said plant corresponding to the claimed nucleic acids remains a complete mystery beyond SEQ ID NOs. 1-10 per se.

Conclusion

It is respectfully submitted that the rejection of all claims in this application is correct and proper for the reasons noted in the rejections above and should be affirmed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)305-3014 or (703)308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 11, 2002

Respectfully Submitted,

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
CONFEREE

ARDIN H. MARSCHEL
PRIMARY EXAMINER

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
Conferee